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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,232	11/20/2003	Mark J. Rosenfeld	3333.2.1.3	9920
28049	7590	01/03/2007		
PATE PIERCE & BAIRD 215 SOUTH STATE STREET, SUITE 550 PARKSIDE TOWER SALT LAKE CITY, UT 84111			EXAMINER ZHANG, NANCY L	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/718,232

Applicant(s)

ROSENFELD ET AL.

Examiner

Nancy L. Zhang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15 and 93-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-15 and 93-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8 sheets.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's amendment along with the election of compound 6-methoxy-2,3-benzoxazolinone as the elected species in the reply filed on 11/15/2006 is acknowledged.

Claims 3-15 and 93-108 are pending and examined.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-15 and 93-108 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the subject of which the claimed composition is administered to. The "mammals" in the preamble of claims 105 and 107 may be implied as being what is meant as the subject of the administration to but this is implied at best. An implied limitation is not clear and concise as required under 112, second paragraph.

Claims 3-15 and 93-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 105 and 107, the phrase "effective amount" renders the claims indefinite because the claims include elements not actually disclosed which could mean the amount being effective for anything, thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). The "promoting weight loss" in the preamble of claims 105 and 107 may be implied as being what is meant for "an effective amount" but this is implied at best. An implied limitation is not clear and concise as required under 112, second paragraph.

Regarding claims 106 and 108, the phrase "a portion" renders the claims indefinite because it is unclear what "a portion" of 6-methoxy-2,3-benzoxazolinone encompasses to be part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 14 and 103, the phrase "including" (line 3) renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 15 and 104, the phrase "comprises adjunctive therapy" renders the claims indefinite because it is unclear what the limitation is because there are multiple interpretations of this recitation as following: (i) the composition further comprises adjunctive therapy drugs for treating a condition selection from the group consisting of arthritis, sleep apnea, fibromyalgia, diabetes, and hyperglycemia; (ii) the composition is useful as an adjunctive therapy drug for treating a condition selection

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from the group consisting of arthritis, sleep apnea, fibromyalgia, diabetes, and hyperglycemia.

For the examination purposes, the recitation of claims 15 and 104 is interpreted as: a process for promoting weight loss in a mammals by administration of a composition comprising 6-methoxy-2,3-benzoxazolinone wherein the composition is "useful as an adjunctive therapy drug for treating a condition selection from the group consisting of arthritis, sleep apnea, fibromyalgia, diabetes, and hyperglycemia".

New Matter Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 106 and 108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 106 and 108 are directed to a process for promoting weight loss in a mammals by administration of a composition comprising 6-methoxy-2,3-benzoxazolinone wherein "at least a portion" of 6-methoxy-2,3-benzoxazolinone is obtained by chemical synthesis.

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The specification only provides statements that the compound 6-methoxy-2,3-benzoxazolinone is obtainable from chemical synthesis. The specification has not provided any description regarding "a portion" of 6-methoxy-2,3-benzoxazolinone is obtained by chemical synthesis or which portion of 6-methoxy-2,3-benzoxazolinone is obtained by chemical synthesis.

This is a new matter rejection.

Scope of Enablement Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoting weight loss by administering 6-methoxy-2,3-benzoxazolinone, does not reasonably provide enablement for therapy in treating arthritis, sleep apnea, fibromyalgia, diabetes and hyperglycemia by administering 6-methoxy-2,3-benzoxazolinone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the

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predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Claims 15 and 104 are directed to a process of administering a composition comprising 6-methoxy-2,3-benzoxazolinone for promoting weight loss and are useful in treating other conditions such as arthritis, sleep apnea, fibromyalgia, diabetes and hyperglycemia.

Given the broadest reasonable interpretation of the claims, the interpretation of the claims 15 and 104 allows for promoting weight loss as well as the treatment of other conditions such as arthritis, sleep apnea, fibromyalgia, diabetes and hyperglycemia by the administration of 6-methoxy-2,3-benzoxazolinone. However, the specification does not sufficiently provide evidence that the compound is effective in treating all of the above diseases. Nor does the specification establish/demonstrate convincing correlations or mechanisms of action between the compound and the claimed disease conditions. The specification only provides working examples for promoting weight loss and treating depression in a mammal by the administration of the compound 6-methoxy-2,3-benzoxazolinone.

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmacy art is high. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the claimed treatment of the instant

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compound. Although it is possible that weight gain/loss in a mammal may be involved to some extent in multitude of diseases mentioned above, it is not known yet that a single underlying mechanism ties together all of the seemingly unrelated manifestations, for example, arthritis and hyperglycemia. Therefore, the skilled artisan would turn to undue amount of trial and error to find out which disease or condition would respond to the administration of said compounds.

Given the breadth of claims 15 and 104, the highly unpredictable state of the art of treating diseases of manifestations, the limited number of working examples and the insufficient amount of guidance present in the specification, one of ordinary skill in the art would have to undergo an undue amount of experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-15 and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Chawan (US PGPub.: 2004/0038909, filing date: Aug. 23, 2002).

Claims 5-15 and 105 are directed to a process for promoting weight loss in a mammals by administration of a composition comprising 6-methoxy-2,3-benzoxazolinone (6-MBOA). Claims 5-13 further limit that 6-methoxy-2,3-benzoxazolinone is obtained from one or more monocotyldenous such as corn; and claim 14 limits that the composition is administered in a manner such as orally by means suitable for ingestion.

Chawan discloses a meal (oral ingestion) for an overweight or obese person comprising a food such as corn (page 6, right column, claim 7, lines 1-3). Since the compound 6-MBOA is a naturally existing substance in varying concentrations in monocotyldenous plants (applicant's specification, page 5, line 16) such as corn, the compound 6-MBOA is inherently present in the food composition comprising corn in the meal disclosed by Chawan.

Therefore, a process of promoting weight loss by administering a composition comprising the compound 6-methoxy-2,3-benzoxazolinone as claimed in claims 5-15 and 105 is known in the art.

With respect to claims 5-13, since there is no extra active step for obtaining the compound 6-MBOA required for the claimed method of treatment, and there is no recitation in the claims to limit the compound being in a certain concentration or in an isolated form in the composition, the recitation in claims 5-15 regarding the process of obtaining the compound 6-MBOA does not limit the claims.

The recitation in claims 8-9 regarding the amount of other chemicals present in the plant is merely a characteristic of the plant and therefore does not limit the claims.

The recitation of "the composition being useful as an adjunctive therapy drug for treating a condition selection from the group consisting of arthritis, sleep apnea, fibromyalgia, diabetes, and hyperglycemia" in claim 15 does not limit the claim because there is no step in the claimed method for treating other conditions and therefore the recitation is a characterization of the composition and does not limit the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NLZ

BRIAN-YONG S. KWON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bri', followed by a long horizontal line extending to the right.